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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
RAO, DEEPAK R	

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1624	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

TH

Office Action Summary	Application No.	Applicant(s)	
	10/507,081	NEWCOMBE ET AL.	
	Examiner	Art Unit	
	Deepak Rao	1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 September 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-21 and 33-38* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-21 and 33-38* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *See Continuation Sheet*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :20040909; 20050131; 20050201; 20050202; 20050203; & 20070215.

DETAILED ACTION

Claims 1-21 and 33-38 are pending in this application.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 33-38 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of treating rheumatoid arthritis, does not reasonably provide enablement for a method for producing a cell cycle inhibitory (anti-cell proliferation) effect; a method for the inhibition of CDK2, CDK4, or CDK6; a method for treating a disease or medical condition selected from cancer, fibroproliferative and differentiative disorders, psoriasis, Kaposi's sarcoma, etc.; or a method for preventing hair loss arising from the treatment of malignant conditions with pharmaceutical agents. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

In evaluating the enablement question, several factors are to be considered. Note *In re Wands*, 8 USPQ2d 1400 and *Ex parte Forman*, 230 USPQ 546. The factors include: 1) The nature of the invention, 2) the state of the prior art, 3) the predictability or lack thereof in the art, 4) the amount of direction or guidance present, 5) the presence or absence of working examples, 6) the breadth of the claims, and 7) the quantity of experimentation needed. The determination that "undue experimentation" would have been needed to make and use the

claimed invention is not a single, simple factual determination. Rather, it is a conclusion reached by weighing all the above noted factual considerations.

The instant claims 33 and 34 are drawn to 'a method of producing a cell cycle inhibitory (anti-cell-proliferation) effect' and 'a method for the inhibition of CDK2, CDK4 or CDK6' and the specification provides that 'in view of the biological properties, the compounds are suitable for treating wide range of diseases' and therefore, the instant claim reads on the corresponding therapeutic effect of the compounds in patients. The specification at page 23 provides that 'the activity of the compounds may be assessed by *in vitro* procedures provided in WO 02/04429' and the specification provides a range of IC_{50} data for the compounds of the invention, however, there is no actual test procedure or the corresponding data for the compounds of the invention. The instant claims however, are drawn to 'a method of producing a cell cycle inhibitory (anti-cell-proliferation) effect' and 'a method for the inhibition of CDK2, CDK4 or CDK6' and thus, drawn to the corresponding treatment associated with the inhibitory activity. The instant claim appears to be a 'reach through' claim. Reach through claims, in general have a format drawn to mechanistic, receptor binding or enzymatic functionality and thereby reach through any or all diseases, disorders or conditions, for which they lack written description and enabling disclosure in the specification thereby requiring undue experimentation for one of skill in the art to practice the invention. As disclosed in the specification, the diseases and disorders encompassed by the instant claims include various types of anti-cell proliferation diseases, leukaemias, fibroproliferative diseases, cancer, bone diseases, etc. some of which have been proven to be extremely difficult to treat. Further, there is no reasonable basis for assuming that the myriad of compounds embraced by the claims will all share the same physiological properties since they

are so structurally dissimilar as to be chemically non-equivalent and there is no basis in the prior art for assuming the same. Note *In re Surrey*, 151 USPQ 724 regarding sufficiency of disclosure for a Markush group.

The instant claims 35-37 are drawn to 'a method of treating a disease or medical condition selected from cancer (solid tumors and leukaemias), fibroproliferative and differentiative disorders, ... '. The instant claims cover disorder/diseases that are known to exist and those that may be discovered in the future, for which there is no enablement provided.

The specification at page 23 provides that 'the activity of the compounds may be assessed by *in vitro* procedures provided in WO 02/04429' and the specification provides a range of IC_{50} data for the compounds of the invention, however, there is no actual test procedure or the corresponding data for the compounds of the invention. The disorders encompassed by the instant claims include diseases caused by the proliferation of tumor cells, etc. some of which have been proven to be extremely difficult to treat. Further, there is no reasonable basis for assuming that the myriad of compounds embraced by the claims will all share the same physiological properties since they are so structurally dissimilar as to be chemically non-equivalent and there is no basis in the prior art for assuming the same. Note *In re Surrey*, 151 USPQ 724 regarding sufficiency of disclosure for a Markush group.

Further, there is no disclosure regarding how the patient in need of such specific kinase inhibiting activity is identified and further, how types of proliferative diseases are treated. See MPEP § 2164.03 for enablement requirements in cases directed to structure-specific arts such as the pharmaceutical art. Receptor activity is generally unpredictable and highly structure specific area, and the data provided of the single compound is insufficient for one of ordinary skill in the

art in order to extrapolate to the other compounds of the claims. It is inconceivable as to how the claimed compounds can treat the extremely difficult diseases embraced by the instant claims. The state of the art is indicative of the unpredictability of the therapeutic approach based on kinase inhibiting activity. Regarding CDK mechanism, Blain et al. (J. of Biol. Chem.) report that "their specific functions are still poorly understood" (see page 25863, col. 1). Also, LuValle et al. (Frontiers in Bioscience) express that "detailed analyses of these pathways are necessary for a complete understanding of chondrocyte proliferation and differentiation" (see page 495, section 4). This is clearly indicative of the fact that the therapeutic role of these kinase inhibitors is very speculative.

Claims 35-37 specifically include, among others, 'a method for treating several types of cancer' - no compound has ever been found to treat cancers of all types generally. Since this assertion is contrary to what is known in medicine, proof must be provided that this revolutionary assertion has merits. The existence of such a "silver bullet" is contrary to our present understanding of oncology. Cecil Textbook of Medicine states that, "each specific type has unique biologic and clinical features that must be appreciated for proper diagnosis, treatment and study" (see the enclosed article, page 1004). A 'disease caused by proliferation of tumor cell' is anything that is caused by abnormal tissue growth. That can be growth by cellular proliferation more rapidly than normal, or continued growth after the stimulus that initiated the new growth has ceased, or lack (partial or complete) of structural organization and/or coordination with surrounding tissue. It can be benign or malignant. Thus, such term covers not only all cancers, but also covers precancerous conditions such as lumps, lesions, polyps, etc. Different types of cancers affect different organs and have different methods of growth and harm

to the body. Also see *In re Buting*, 163 USPQ 689 (CCPA 1969), wherein 'evidence involving a single compound and two types of cancer, was held insufficient to establish the utility of the claims directed to disparate types of cancers'. Thus, it is beyond the skill of oncologists today to get an agent to be effective against cancers or disorders caused by kinases generally.

Further, there is no established single antiproliferative therapeutic agent for all these types of diseases, which are characterized by the proliferation of tumor cells. The ideal chemotherapeutic drug would target and destroy only cancer cells without adverse effects or toxicities on normal cells. Unfortunately, no such drug exists; there is a narrow therapeutic index between cell kill of cancer cells and that of normal cells. Successful treatment of cancer requires elimination of all cancer cells, whether at the primary site, extended to local-regional areas, or metastatic to other regions of the body. The major modalities of therapy are surgery and radiotherapy (for local and local-regional disease) and chemotherapy (for systemic sites). For example, regarding the treatment of leukemia, The Merck Manual (online edition) states, that "Treatment programs and clinical situations are complex". Dosage regimen is dependent on several risk factors and the contribution of each active ingredient of a multidrug combination therapy is complex and unclear. Similarly, Myelodysplastic syndrome (MDS) is characterized by clonal proliferation of hematopoietic cells, including erythroid, myeloid, and megakaryocytic forms and its incidence is unknown and further, there is no established treatment. Several growth factors and their receptors have been associated with glioma and the treatment depends on the pathology and location and is often multimodal.

Atherosclerosis is a common form of arteriosclerosis associated with the formation of atheromas, which are deposits of yellow plaques containing cholesterol, lipids, and lipophages

within the intima and inner media of arteries. This, results in a narrowing of the arteries, which reduces the blood and oxygen flow to the heart and brain as well as to other parts of the body and can lead to a heart attack, stroke, or loss of function or gangrene of other tissues.

Further, there is no disclosure regarding how the patient in need of such specific CDK inhibiting activity is identified and further, how types of cancers, autoimmune diseases, bone diseases, etc. are treated. See MPEP § 2164.03 for enablement requirements in cases directed to structure-specific arts such as the pharmaceutical art. Receptor activity is generally unpredictable and highly structure specific area, and the data provided of the single compound is insufficient for one of ordinary skill in the art in order to extrapolate to the other compounds of the claims. It is inconceivable as to how the claimed compounds can treat the extremely difficult diseases embraced by the instant claims.

Applicants have not provided any competent evidence or disclosed tests that are highly predictive for the pharmaceutical use of the instant compounds. Pharmacological activity in general is a very unpredictable area. Note that in cases involving physiological activity such as the instant case, "the scope of enablement obviously varies inversely with the degree of unpredictability of the factors involved". See *In re Fisher*, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970).

Claim 38 is specifically drawn to 'a method for preventing hair loss arising from the treatment of malignant conditions with pharmaceutical agents'. The specification does not provide sufficient guidance towards enablement of the instant claim. The instant compounds are disclosed to have cell cycle inhibitory and there by useful as pharmaceutical therapeutic agents in the treatment of cancers, etc. Along with this activity, as per the instant claim, the compounds

are also intended for 'preventing hair loss', which 'hair loss' is a common side effect of chemotherapy. The specification provides the following guidance towards the instantly claimed method of use:

> Preventing cells from entering DNA synthesis by inhibition of essential S-phase initiating activities such as CDK2 initiation may also be useful in protecting normal cells of the body from toxicity of cycle-specific pharmaceutical agents. Inhibition of CDK2 or 4 will prevent progression into the cell cycle in normal cells which could limit the toxicity of cycle-specific pharmaceutical agents which act in S-phase, G2 or mitosis. Such protection may result in the prevention of hair loss normally associated with these agents..

As can be seen from above, the 'method for preventing hair loss' is only a contemplated activity for the claimed compounds. The specification does not provide any conclusive evidence of such 'hair loss prevention' activity. "Chemotherapy often causes hair loss otherwise known as Alopecia. This is because the cells in the hair follicles grow fast and chemotherapy damages fast growing cells. Hair loss is not permanent and it will grow back once your treatment has ended. Not all drugs cause hair loss - Some just cause thinning and others cause dramatic hair loss including the body hair and eyebrows. Furthermore, different people have different tolerances to the drugs", see http://www.cancernet.co.uk/hairloss.htm. As can be seen from the state of the art, there is no way to tell if someone will lose hair during chemotherapy. Hair loss depends on the administered drug, the dosages, etc. Currently there are no pharmaceutical therapeutic agents known in the art that treat all types of cancer, atherosclerosis, bone diseases, etc. as well as provide prevention of hair loss.

(Only a few of the claimed diseases are discussed here to make the point of an insufficient disclosure, it does not definitely mean that the other diseases meet the enablement requirements). There is no evidence of record, which would enable the skilled artisan in the

identification of the people who have the potential of becoming afflicted with the disease(s) or disorder(s) claimed herein.

In evaluating the enablement question, several factors are to be considered. Note *In re Wands*, 8 USPQ2d 1400 and *Ex parte Forman*, 230 USPQ 546. The factors include: 1) The nature of the invention, 2) the state of the prior art, 3) the predictability or lack thereof in the art, 4) the amount of direction or guidance present, 5) the presence or absence of working examples, 6) the breadth of the claims, and 7) the quantity of experimentation needed.

1) The nature of the invention: Therapeutic use of the compounds in treating a kinase mediated disease.

2) The state of the prior art: There are no known compounds of similar structure which have been demonstrated to treat patients suffering from all types of diverse diseases mediated by kinases. In reference to cancer treatment using protein tyrosine kinase inhibitors, Traxler (Exp. Opin. Ther. Patents, 1997) stated that 'pharmacological properties such as stability in biological media, bioavailability, metabolism or formulability are significant hurdles' see page 585, col. 2, lines 33-36.

3) The predictability or lack thereof in the art: Applicant has not provided any competent evidence or disclosed tests that are highly predictive for the pharmaceutical use of the instant compounds. Pharmacological activity in general is a very unpredictable area. Note that in cases involving physiological activity such as the instant case, 'the scope of enablement obviously varies inversely with the degree of unpredictability of the factors involved'. See *In re Fisher*, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970).

4) The amount of direction or guidance present and 5) the presence or absence of working examples: There are no doses present to direct one of ordinary skill in the art to use the compounds in the treatment of all of the diseases or disease symptoms within the scope of the claims. The specification provides a source for test procedures for the measurement of CDK kinase inhibitory activity of the compounds and a possible IC_{50} range for the compounds of the invention. However, there is disclosure regarding how this data correlates to the inhibition of all types of kinases and/or to the treatment of all diseases mediated by kinases.

6) The breadth of the claims: The instant claims embrace inhibiting kinase activity in general and treating kinase mediated diseases in general.

7) The quantity of experimentation needed would be an undue burden, because it is not known what type of 'diseases' are referred to in the claims. Further, it would be an undue burden on one skilled in the pharmaceutical arts since there is inadequate guidance given to the skilled artisan, regarding the medical conditions or illnesses included in the instant claims.

It is inconceivable as to how the claimed compounds can treat the large list of diseases associated with the instantly claimed activity of CDK inhibition. Further, there is no disclosure regarding how the patient in need of the treatment requiring the specific kinase inhibiting activity is identified and further, how all types of the diseases having diverse mechanisms are treated. The state of the art is indicative of the unpredictability of the therapeutic approach based on kinase inhibiting activity, see Blain et al. and LuValle et al. previously cited.

Thus, factors such as "sufficient working examples", "the level of skill in the art" and "predictability", etc. have been demonstrated to be sufficiently lacking in the use of the invention. In view of the breadth of the claim, the chemical nature of the invention, the

unpredictability of ligand-receptor interactions in general, and the lack of working examples regarding the activity of the claimed compounds, one having ordinary skill in the art would have to undergo an undue amount of experimentation to use the invention commensurate in scope with the claims.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-21 and 33-38 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The following reasons apply:

1. In claim 1, the structural formula (IC) appears to represent a tricyclic ring wherein the pyrimidine and the imidazole ring are fused together by a 6-membered ring with R^2 as a ring member. The claim, however, provides the definition of R^2 as a monovalent substituent - hydrogen, halo or cyano. Clear structural representation is suggested.
2. In claim 1, following formula (IE), a definition is provided for the term " R^5 ", however, the structural formula does not show the presence of the above term. The specification at page 5 also contains the same discrepancy.
3. Claims 3, 5, 8, 11, 14, 17 and 20 recite "A compound of formula ...", however, the claims do not contain the structural formula recited in the claim. An independent claim must contain all limitations within the claim or should depend from another claim containing the formula.

(The claims not particularly addressed above are included in the rejection as they are dependent claims).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

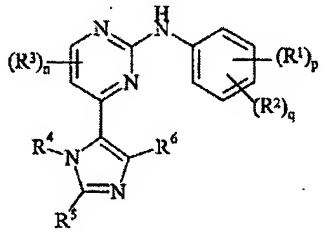
This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

1. Claims 1-21 and 33-38 are rejected under 35 U.S.C. 103(a) as being obvious over Breault et al., WO 02/20512 (published March 14, 2002).

The reference generically teaches imidazolo-5-yl-2-anilino-pyrimidine compounds having cell cycle inhibitory activity, see formula (I) in page 2 and the compounds of the Examples. The instant claims differ from the reference by reciting specific species or a more limited subgenus than the reference. It would have been obvious to one having ordinary skill in the art at the time of the invention to select any of the species of the genus taught by the reference, including those instantly claimed, because the skilled chemist would have the reasonable expectation that any of the species of the genus would have similar properties and, thus, the same use as taught for the genus as a whole i.e., as therapeutic agents. One of ordinary

skill in the art would have been motivated to select the claimed compounds from the genus in the reference since such compounds would have been suggested by the reference as a whole. It has been held that a prior art disclosed genus of useful compounds is sufficient to render prima facie obvious a species falling within a genus.

The reference discloses a genus having the following structural formula:

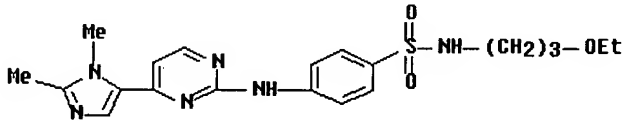


(I)

wherein R^2 is a group R^a-R^b- wherein R^b is $-SO_2$-NH- and R^a is as defined in page 3. The reference further discloses several compounds that fall within this subgenus.

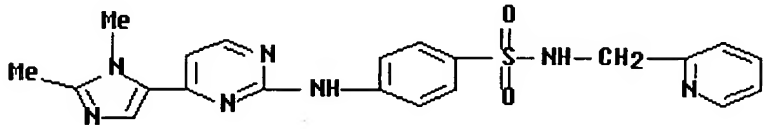
For example, the reference discloses the following compounds:

Example 97



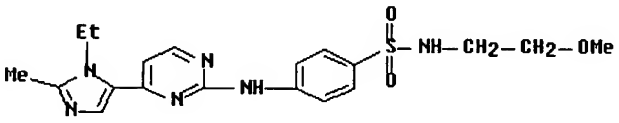
The instant claim recites a compound of formula (IA) wherein R^1 is 1-ethoxyprop-2-yl, which compound is structurally analogous to the reference disclosed compound.

Example 93



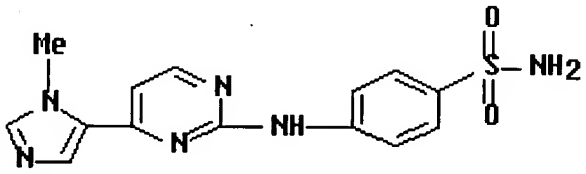
The instant claim recites a compound of formula (IB) having a 1-ethyl-2-methyl-imidazolyl group attached to the pyrimidine wherein R^1 is pyrid-2-ylmethyl. Therefore, the compound according to formula (IB) differs from the reference disclosed compound by having an ethyl (CH_2CH_3) in place of a methyl (CH_3) substituent, i.e., differs by a CH_2 group.

Example 37



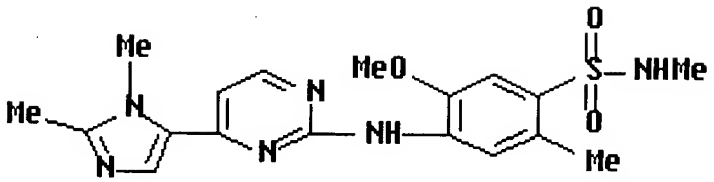
The instant claim recites a compound of formula (IC) having a 1-isopropyl-2-methyl-imidazolyl attached to the pyrimidine. The compound according to formula (IC) differs from the reference disclosed compound by having an isopropyl [$-CH(CH_3)_2$] in place of an ethyl (CH_2CH_3) substituent, i.e., differs by a CH_2 group.

Example 15



The instant claims recite a compound of formula (ID) wherein the substituent R^3 which is at the 1-position of the imidazolyl is recited to be $C_{2\text{-}6}$alkyl, e.g., an ethyl group ($-CH_2\text{-}CH_3$), and therefore, the instant claims include compounds differ from the reference disclosed compound of, say Example 15, by having an ethyl in place of methyl substituent or by a CH_2 group.

Example 161



The instant claims recite a compound of formula (IE), however, exclude reference disclosed compound of Example 161, see the proviso statement following structural formula (IE). The instantly claimed compounds according to structural formula (IE), however, include compounds, for example, wherein one of the R^2 is ethyl or ethoxy; or R^4 is ethyl; etc. Therefore, the instantly claimed compounds differ from the reference compounds by a CH_2 group.

It is well established that compounds that differ by a CH_2 group are structural homologs. It would have been obvious to one having ordinary skill in the art at the time of the invention to modify the reference compounds to prepare the structural homolog. One having ordinary skill in the art would have been motivated to prepare the instantly claimed compounds because such structurally homologous compounds are expected to possess similar properties. It has been held that compounds that are structurally homologous to prior art compounds are *prima facie* obvious, absent a showing of unexpected results. *In re Hass*, 60 USPQ 544 (CCPA 1944); *In re Henze*, 85 USPQ 261 (CCPA 1950).

Note: Applicant cannot rely on foreign priority based on GB 0205693.5 (filed March 9, 2002) to overcome the rejection because the priority document does not fully support the instant claims. Specifically, the priority document does not support the definitions provided for various variables under each of the structural formula, some of the terms that lack support are listed here: under formula (IA) the instant claims recite the limitation that "or R^1 and R^2 together form 2,2-

dimethylaziridin-1-yl"; under formula (IB) – R^1 in the instant claims includes the terms " 2-phenoxyethyl, 2-(4-methoxyphenoxy)ethyl, ... 2-(propoxy)ethyl "; etc.

2. Claims 1-21 and 33-38 are rejected under 35 U.S.C. 103(a) as being obvious over Breault et al., WO 02/20512 or U.S. 6,969,714 (International Application filing date August 30, 2001).

The applied reference has a common assignee and/or inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). This rejection might also be overcome by showing that the reference is disqualified under 35 U.S.C. 103(c) as prior art in a rejection under 35 U.S.C. 103(a). See MPEP § 706.02(l)(1) and § 706.02(l)(2).

The reasons provided above apply here and are incorporated by reference.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or

improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

1. Claims 1-21 and 33-38 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-15 of U.S. Patent No. 6,969,714. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instantly claimed compounds are structurally analogous to the reference compounds. See the reasons provided above for the rejection under 35 U.S.C. 103.

2. Claims 1-21 and 33-37 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-21 of copending Application No. 10/507,163. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instantly claimed compounds are structurally analogous to reference compounds. The reference claims are also drawn to imidazolo-5-yl-2-anilino-pyrimidine compounds having cell cycle inhibitory activity. It would have been obvious

to one having ordinary skill in the art at the time of the invention to select any of the species of the genus taught by the reference, including those instantly claimed, because the skilled chemist would have the reasonable expectation that any of the species of the genus would have similar properties and, thus, the same use as taught for the genus as a whole i.e., as therapeutic agents. One of ordinary skill in the art would have been motivated to select the claimed compounds from the genus in the reference since such compounds would have been suggested by the reference as a whole. It has been held that a prior art disclosed genus of useful compounds is sufficient to render prima facie obvious a species falling within a genus.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

3. Claims 1-21 and 33-37 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-20 of copending Application No. 10/507,169. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instantly claimed compounds are structurally analogous to reference compounds. The reference claims are also drawn to imidazolo-5-yl-2-anilino-pyrimidine compounds having cell cycle inhibitory activity. It would have been obvious to one having ordinary skill in the art at the time of the invention to select any of the species of the genus taught by the reference, including those instantly claimed, because the skilled chemist would have the reasonable expectation that any of the species of the genus would have similar properties and, thus, the same use as taught for the genus as a whole i.e., as therapeutic agents. One of ordinary skill in the art would have been motivated to select the claimed compounds from

the genus in the reference since such compounds would have been suggested by the reference as a whole. It has been held that a prior art disclosed genus of useful compounds is sufficient to render prima facie obvious a species falling within a genus.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Receipt is acknowledged of the Information Disclosure Statements filed on September 9, 2004; January 31, February 1, February 2, February 3, 2005; and February 15, 2007 and copies are enclosed herewith.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deepak Rao whose telephone number is (571) 272-0672. The examiner can normally be reached on Monday-Friday from 8:00am to 5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson, can be reached at (571) 272-0661. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR

system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Deepak Rao
Primary Examiner
Art Unit 1624

May 11, 2007